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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,521	09/29/2006	Chae-Ok Yun	30082U	1275

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EXAMINER	
HILL, KEVIN KAI	
ART UNIT	**PAPER NUMBER**
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/599,521	YUN ET AL.
	Examiner	Art Unit
	KEVIN HILL	1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2010* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 14, 2010 has been entered.

Election/Restrictions

Applicant's response to the Requirement for Restriction, filed on April 16, 2009 is acknowledged.

Applicant has elected the invention of Group III, claim(s) 7 and 13, drawn to methods of delivering a gene into cells and treating a cancer, the methods comprising administering a gene delivery system comprising a Relaxin-encoding nucleotide sequence.

Amendments

Applicant's response and amendments, filed October 14, 2010, to the prior Office Action is acknowledged. Applicant has cancelled Claims 1-26 and added new claims, Claims 27-38.

Claims 27-38 are under consideration.

Priority

This application is a 371 of PCT/KR05/00921 filed on March 30, 2005. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d).

Acknowledgment is made of Applicant's claim for foreign priority based on an application filed in The Republic of Korea on March 30, 2004. A certified copy of KR 10-2004-0021601 and a certified translation of the foreign priority document has been filed with the instant application.

Examiner's Note

Unless otherwise indicated, previous objections/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the October 14, 2010 response will be addressed to the extent that they apply to current rejection(s).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

1. **Applicant's submission of color drawings**, and a corresponding amendment to the Specification referring to said color drawings, in the papers filed October 14, 2010 is acknowledged.

Applicant's petition for acceptance of color drawings under 37 C.F.R. §1.84(a)(2) and (b)(2) are accepted.

/Joseph T. Woitach/

Supervisory Patent Examiner, Art Unit 1633

Claim Rejections - 35 USC § 102

2. **The prior rejection of Claims 17-23 under 35 U.S.C. 102(b) and 35 U.S.C. 102(e)** as being anticipated by Hirsch et al (U.S. 2003/0003583) **is withdrawn** in light of Applicant's cancellation of the claims.

3. **Claims 27-31 and 33-35 are rejected under 35 U.S.C. 102(b) and 35 U.S.C. 102(e)** as being anticipated by Hirsch et al (U.S. 2003/0003583).

While Applicant has changed the claim numbers with the new claim set, the limitations of instant Claims 27-31 and 33-35 were recited in prior Claims 17-21 and 23 and previously rejected. The disclosure of Hirsch et al is provided in prior Office Actions and will not be iterated herein.

Response to Arguments

Applicant argues that the key feature of the AAV of Hirsch et al. exists in the point that the induction of a therapeutic gene expression in the recombinant AAV is conducted by the administration of a proteasome inhibitor. The method of Hirsch et al. to deliver a selected gene to a cell and to regulate its expression is therefore accomplished only when the cell or tissue is contacted with a proteasome inhibitor.

Applicant's argument(s) has been fully considered, but is not persuasive. For expression, the transgene is operably linked to a promoter [0015]. Figures 1 and 3-4 show that the transgene is expressed from the adenoviral vector in the absence of proteosome inhibitor. Thus, regulation of transgene expression is **not** 'accomplished only when the cell or tissue is contacted with a

proteasome inhibitor'. Rather, the proteosome inhibitor merely enhances transgene expression [0027], and was previously recognized in the art to enhance AAV transduction efficiency [0152-0153].

Applicant argues that Hirsch et al. do not teach a method for enhancing the transduction efficiency of a recombinant virus or for enhancing apoptosis in a tumor cell by using a relaxin-encoding nucleotide sequence operatively linked to a regulatory sequence directing its expression, where the relaxin protein expressed thereby enhances transduction efficiency or enhances apoptosis in a tumor cell. No teaching or suggestion of the use of relaxin to enhance the transduction efficiency of a gene delivery system or to enhance apoptosis in a tumor cell is found in Hirsch et al. Hirsch et al. do not, expressly or inherently, teach the enhancement of the transduction efficiency of a gene delivery system by the expressed relaxin protein.

Applicant's argument(s) has been fully considered, but is not persuasive. The only active step of the instantly claimed method is the administration of an AAV encoding Relaxin. Hirsch et al disclose a method of delivering a gene into cells for the treatment of cancer [0151], the method comprising the use of an adenoviral gene delivery system [0019], wherein the gene encodes Relaxin [0140]. Thus, Hirsch et al anticipates the claimed method step.

With respect to the intended use limitations "enhancing transduction efficiency" (Claim 27) and "enhancing apoptosis" (Claim 33), such are considered functional properties inherent to the Relaxin protein expressed by the gene delivery system, absent evidence to the contrary. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See MPEP §2114.

"Products of identical chemical composition cannot have mutual exclusive properties." A compound and its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)). Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure [Relaxin protein encoded by a relaxin gene], the disclosed properties are necessarily present. *In re Spada*, 911

F.2d 705,709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP §2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure *at the time of invention*, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."); *Abbott Labs v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1319, 51 USPQ2d 1307, 1310 (Fed.Cir.1999) ("If a product that is offered for sale inherently possesses each of the limitations of the claims, then the invention is on sale, whether or not the parties to the transaction recognize that the product possesses the claimed characteristics."); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342, 1348-49 (Fed. Cir. 1999) ("Because 'sufficient aeration' was inherent in the prior art, it is irrelevant that the prior art did not recognize the key aspect of [the] invention.... An inherent structure, composition, or function is not necessarily known.")>; *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44, 74 USPQ2d 1398, 1406-07 (Fed. Cir. 2005)

The discovery of a new use for an old structure based on unknown properties of the structure might be patentable to the discoverer as a process of using. *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). However, when the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May,* 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978) (Claims 1 and 6, directed to a method of effecting nonaddictive analgesia (pain reduction) in animals, were found to be anticipated by the applied prior art which disclosed the same compounds for effecting analgesia but which was silent as to addiction. The court upheld

the rejection and stated that the applicants had merely found a new property of the compound and such a discovery did not constitute a new use.

Applicant argues that the relaxin gene, if contained in the recombinant AAV of Hirsch et al., does not exert such functions as required by the present claims because it cannot be expressed in the transduced cells without introduction of proteasome inhibitors.

Applicant's argument(s) has been fully considered, but is not persuasive. Arguments of counsel cannot take the place of **factually supported objective evidence** in the record. See *In re Schulze*, 346 F.2d 500, 602, 145 USPQ 716, 718 (CCPA 1965), *In re Huang*, 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689 (Fed. Cir. 1996); *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984).

Attorney statements regarding, e.g. inoperability of the prior art, are not evidence without a supporting declaration. Applicant is respectfully reminded that Figures 1 and 3-4 of Hirsch et al clearly evidence that transgene expression occurs in the absence of proteosome inhibitors. Thus, the recombinant AAV encoding a Relaxin transgene of Hirsch et al possesses the property of enhancing the transduction efficiency of the recombinant virus because the AAV itself can express the target gene without administration of proteosome inhibitors or adenovirus helper virus.

Claim Rejections - 35 USC § 103

4. **The prior rejection of Claims 22 and 24-26 under 35 U.S.C. 103(a)** as being unpatentable over Hirsch et al (U.S. 2003/0003583) in view of Hallenbeck et al (U.S. Patent 5,998,205) and Dalemans et al (U.S. Patent 6,136,594) **is withdrawn** in light of Applicant's cancellation of the claims.

5. **Claims 32 and 36-38 are rejected under 35 U.S.C. 103(a)** as being unpatentable over Hirsch et al (U.S. 2003/0003583) in view of Hallenbeck et al (U.S. Patent 5,998,205) and Dalemans et al (U.S. Patent 6,136,594).

While Applicant has changed the claim numbers with the new claim set, the limitations of instant Claims 32 and 36-38 were recited in prior Claims 22 and 24-26 and previously rejected. The disclosure of Hallenbeck et al and Dalemans et al is provided in a prior Office Action and will not be iterated herein.

Response to Arguments

Applicant argues that neither Hallenbeck et al nor Dalemans et al do not cure the defect of Hirsch et al.

Applicant's argument(s) has been fully considered, but is not persuasive. The Examiner's response to Applicant's argument(s) regarding Hirsch et al are discussed above and incorporated herein. Applicant does not contest the teachings of Hallenbeck et al and Dalemans et al as applied to the obviousness to substitute a first adenovirus expression vector as taught by Hirsch et al with a second adenovirus expression vector comprising a deletion of the E3 region into which the relaxin-encoding nucleotide is inserted, inactivation of the E1B 19 and/or E1B 55 genes, and/or an active E1A gene as taught by Hallenbeck et al and Dalemans et al with a reasonable expectation of success because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Conclusion

6. No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP §706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to KEVIN K. HILL whose telephone number is (571)272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-5:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/
Examiner, Art Unit 1633